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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,203	09/14/2000	Nicholas Charles Alan Smith	1171/38911/80	5874

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EXAMINER

DAWSON, GLENN K

ART UNIT

PAPER NUMBER

3761

15

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/662,203	SMITH ET AL.
	Examiner Glenn K Dawson	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 December 2003.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-7 is/are allowed.
- 6) Claim(s) 8-13 is/are rejected.
- 7) Claim(s) 14-21 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8,10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Elam, et al-4088131.

Elam discloses a device having a body portion with a 1<sup>st</sup> opening 36 in communication with a gas supply 18, a 2<sup>nd</sup> opening 26 in communication with a user. The gas is delivered from the 1<sup>st</sup> opening to the 2<sup>nd</sup> opening during inhalation, but a valve redirects air from the supply and 1<sup>st</sup> opening to go through 1<sup>st</sup> and 2<sup>nd</sup> auxiliary openings 30 during exhalation so that excess breathing gas is vented to the atmosphere.

The gas supply is a conventional oxygen tank which clearly has the ability to supply oxygen gas continuously at a pressure above ambient. In addition, col. 4 lines 52-56, it is clear that gas is being delivered by the source continuously.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9,11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elam, et al.-'131.

Elam discloses the invention as claimed with the exception of the humidification means. As it is well-known in the art to humidify inhalation gases, to have provided such a means in Elam's device would have been an obvious design choice in order to provide moister air which is easier to breathe for certain patients.

Evidence of prior art which shows it was known in the art to provide humidified gas to be breathed would be Boussignac, et al.-'002.

***Allowable Subject Matter***

Claims 14-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-7 are allowed.

***Response to Arguments***

Applicant's arguments filed 12-12-03 have been fully considered but they are not persuasive.

The previous statements by the examiner regarding the oxygen gas pressure are not contradictory. Even though the Elam device need not provide positive pressure to the patient during exhalation, the device clearly has the ability to do so. The examiner is not contending that it would have been obvious to do so, only that the device has the ability to do so, which is all that is required of the claim. There is no limitation that the gas received by the patient is continuous and above ambient pressure. However, the examiner contends that this would be the case especially given the fact that the pressure of the gas would be increased during compression of the bag 14. In any event, the supply of oxygen through port 36 is continuous and above ambient pressure. And is delivered to the patient during inhalation and is directed out ports 30 during exhalation.

The claim also does not stipulate that the device is for use with spontaneously breathing patients. However, it should be noted that col. 4 lines 19-8 details the inflation and exhalation of the gas by the patient and col. 5 lines 59-66 state that the device can be used once the patient has resumed breathing under his own power.

The humidification means could be placed downstream of the bag, as taught by Boussignac, and therefore condensation inside the bag would not occur.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Glenn K Dawson  
Primary Examiner  
Art Unit 3761

Gkd  
27 February 2004